

SUBSTITUTE FORM PTO-1449
(MODIFIED)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT
(Use several sheets if necessary)

ATTY. DOCKET NO.
06275/034001

SERIAL NO.
08/601,005

APPLICANT
Kjell Bäckström et al.

FILING DATE
March 1, 1996

GROUP
1615

(37 CFR 1.98(b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER			ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
PJ	AA	5	2	2	5	1	8	3	7/6/93
	AB								
	AC								
	AD								
	AE								
	AF								
	AG								
	AH								
	AI								
	AJ								
	AK								

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION
							YES
PJ	AL	WO 91/11495	8/8/91	PCT WO			X
PJ	AM	0 518 600 A1	12/16/92	European Europe			
	AN						
	AO						
	AP						

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

AQ			
AR			
AS			
EXAMINER	BAWT	DATE CONSIDERED	9/22/98
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
Substituted Disclosure Form (PTO-1449)			

SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 06275/034001	SERIAL NO. 08/601,005								
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98(b))				APPLICANT Kjell Backstrom et al.									
				FILING DATE March 1, 1996	GROUP								
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL		PATENT NUMBER			ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE				
PD	AA	3	0	1	4	8	4	4	12/26/61	Thiel et al.	167	82	
	AB	3	6	3	2	7	4	3	01/04/72	Geller et al.	424	45	
	AC	4	2	3	2	0	0	2	11/04/80	Nogrady	424	45	
	AD	4	5	4	8	9	2	2	10/22/85	Carey et al.	514	4	
	AE	4	6	1	3	5	0	0	09/23/86	Suzuki et al.	429	85	
	AF	4	6	9	0	9	5	2	09/01/87	Kagatani et al.	514	808	
	AG	4	7	4	6	5	0	8	05/24/88	Carey et al.	424	88	
	AH	4	7	8	8	2	2	1	11/29/88	Kagatani et al.	514	808	
	AI	4	7	9	4	0	0	0	12/27/88	Ecanow	424	457	
	AJ	4	8	4	7	2	9	8	07/11/89	Alexander et al.	514	565	
PD	AK	4	8	4	9	4	0	5	07/18/89	Ecanow	514	3	
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION													
		DOCUMENT NUMBER		PUBLICATION DATE	COUNTRY OR PATENT OFFICE		CLASS	SUBCLASS	TRANSLATION				
									YES	NO			
PD	AL	837,465		15 JUN 60	GB								
	AM	WO 92/08446		29 MAY 92	-PCT- WO								
	AN	WO 91/04011		04 APR 91	-PCT- WO								
	AO	0 499 344 A2		27 NOV 89	-EP- Europe								
	AP	WO 91/16038		31 OCT 91	-PCT- WO								
	AQ	WO 91/14422		03 OCT 91	-PCT- WO								
	AR	26 20 446.6		08 MAY 76	Germany								
	AS	0 200 383		07 APR 86	-EP- Europe								
	AT	0 360 340		18 SEP 89	-EP- Europe								
PD	AU	8007820-7		17 NOV 86	Sweden								
EXAMINER BAWA						DATE CONSIDERED			9/22/98				
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 06275/034001		SERIAL NO. 08/601,005							
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98(b))				APPLICANT Kjell Backstrom et al.									
				FILING DATE March 1, 1996		GROUP							
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL		PATENT NUMBER			ISSUE DATE	PATENTEE		CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
Q-13	BA	4	8	9	5	7	1	9	01/23/90	Radhakrishnan et al.	424	45	
	BB	4	9	0	0	7	3	0	02/13/90	Miyauchi	514	12	
	BC	4	9	5	9	3	5	8	09/28/88	Carey et al.	514	171	
	BD	4	9	6	3	3	6	7	10/16/90	Ecanow	424	485	
	BE	4	9	9	4	4	3	9	02/19/91	Longenecker et al.	514	3	
	BF	5	0	0	6	3	4	3	04/09/91	Benson et al.	424	450	
	BG	5	0	1	1	6	7	8	04/30/91	Wang et al.	424	45	
	BH	5	1	1	8	4	9	4	06/02/92	Schultz et al.	424	45	
	BI	5	1	2	2	3	7	6	06/16/92	Aliverti et al.	424	405	
	BJ	5	1	7	9	0	7	9	01/12/93	Hansen et al.	514	4	
Q-13	BK	5	2	0	0	3	9	3	04/06/93	Weiner	514	3	
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION													
		DOCUMENT NUMBER		PUBLICATION DATE	COUNTRY OR PATENT OFFICE		CLASS	SUBCLASS	TRANSLATION				
									YES	NO			
Q-17	BL	1 527 605		04 OCT 78	-GB	Britain							
	BM	0 272 097		15 DEC 87	-EP	Europe							
	BN	WO-88/09163		01 DEC 88	-PCT	WO							
	BO	0 225 189		28 NOV 86	-EP	Europe							
	BP	WO 94/07514		14 APR 94	-PCT	WO							
	BQ	261 096 A1		20 MAY 83	Germany								
	BR	WO 90/07333		12 JUL 90	-PCT	WO							
	BS	0 055 041		03 DEC 81	-EP	Europe							
	BT	1 208 036		19 NOV 63	Germany								
Q-13	BU	26 20 483		23 DEC 76	Germany								
EXAMINER Bawa						DATE CONSIDERED			9/22/98				
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 06275/034001	SERIAL NO. 08/601,005								
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98(b))		APPLICANT Kjell Backstrom et al.											
		FILING DATE March 1, 1996		GROUP									
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL		PATENT NUMBER		ISSUE DATE	PATENTEE		CLASS	SUBCLASS	FILING DATE IF APPROPRIATE				
✓-B	CA	5	2	0	2	1	2	9	04/13/93	Samejima et al.	424	489	
	CB	5	2	8	4	6	5	6	02/08/94	Platz et al.	424	435	
	CC	5	3	0	6	4	8	3	04/26/94	Mautone	424	45	
	CD	5	3	4	8	7	3	0	09/20/94	Greenleaf et al.	424	45	
	CE	5	3	5	4	5	6	2	10/11/94	Platz et al.	424	489	
	CF	5	3	6	4	8	3	8	11/15/94	Rubsamen	514	3	
	CG	5	5	0	6	2	0	3	04/09/96	Backstrom et al.	514	4	
	CH	5	5	1	4	6	7	0	05/07/96	Friedman et al.	514	2	
✓-B	CI	5	5	1	8	9	9	8	05/21/96	Backstrom et al.	514	3	
	CJ												
	CK												
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION													
		DOCUMENT NUMBER		PUBLICATION DATE	COUNTRY OR PATENT OFFICE		CLASS	SUBCLASS	TRANSLATION				
									YES	NO			
✓-B	CL	76 36431		03 DEC 76	France								
	CM	0 130 550		27 JUN 84	EP Europe								
	CN	0 133 252		19 JUL 84	EP Europe								
	CO	WO 91/11495		08 AUG 91	PCT WO								
	CP	0 518 600 A1		08 JUN 92	EP Europe								
	CQ	9400371-2		04 FEB 94	Sweden								
✓-B	CR	9302198-8		16 MAY 94	Sweden								
	CS												
EXAMINER BSAWA					DATE CONSIDERED			9/22/98					
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.													

SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 06275/034001	SERIAL NO. 08/601,005
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		APPLICANT Kjell Backstrom et al.		
(37 CFR 1.98(b))		FILING DATE March 1, 1996		GROUP

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

Q.17	DA	Allenby et al., "The absorption of Insulin Across the Respiratory Tract of the Guinea-Pig" The Aerosol Society, Fourth Annual Conference, University of Surrey, Apr. 9-11, 1990.
		Aungst et al., "Comparison of the effects of various transmucosal absorption promoters of buccal insulin delivery" Int. J. Pharm. (Netherlands) 53(3):227-235, 1989. (abstract)
	DC	Bjork, "Starch Microspheres as a Nasal Delivery System for Drugs" ACTA Universitatis Upsaliensis 103, 1993.
	DD	Bjork et al., "Degradable starch microspheres as a nasal delivery system for insulin" Int. J. Pharm 47: 233-238, 1988.
		Chandler et al., "Nasal absorption in rats. II Effect of enhancers on insulin absorption and nasal histology" Int. J. Pharm 76:61-70, 1991.
	DF	Cutie et al., "The Role of Dispersing Agents in Inhalation and Intranasal Aerosol Suspensions" Aerosol Age, pp. 52-54, 1985.
	DG	Damasy et al., "Intranasal Insulin" Diabetes Res. and Clin. Pract. 5:S163, 1988.
	DH	Edman et al., "Routes of Delivery: Case Studies:Nasal Delivery of Peptide Drugs" Advanced Drug Del. Rev. 8:165-177, 1992.
	DI	Gordon et al., "Nasal absorption of insulin: Enhancement by hydrophobic bile salts" Proc. Natl. Acad. Sci. 32:7419-7423, 1985.
	DJ	Hirai et al., "Effect of Surfactants on the Nasal Absorption of Insulin in Rats" Int. J. Pharm. 9:165-172, 1981.
	DK	Igawa et al., "Effect of Absorption Promoters in Intranasal Administration of Human Fibroblast Interferon.." Chem Pharm. Bull. 37:418-421, 1989.
Q.18	DL	Komada et al., "Intratracheal Delivery of Peptide and Protein Agents: Absorption from Solution and Dry Powder by Rat Lung" J. Pharm. Sciences 83:863, 1994.

EXAMINER

B AWA

DATE CONSIDERED

9/22/98

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 06275/034001	SERIAL NO. 08/601,005
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)				APPLICANT Kjell Backstrom et al.	
(37 CFR 1.98(b))				FILING DATE March 1, 1996	GROUP
OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)					
Q.B	EA	Lee et al., "Mucosal Penetration Enhancers for Facilitation of Peptide and Protein Drug Absorption" Crit. Rev. Therapeutic Drug Carrier Systems 8(2):91-192, 1991.			
	EB	Lee et al., "Intranasal Bioavailability of Insulin Powder Formulations..." J. Pharm. Sciences 80(8):725, 1991.			
	EC	Mishima et al., "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption..." J. Pharma. Dyn. 10:624-631, 1987.			
	ED	Morita et al., "Effects of Various Absorption Promoters on Pulmonary Absorption of Drugs..." Biol. Pharm. Bull. 16:269-262, 1993.			
	EE	Moses et al., "Insulin Administered Intranasally as an Insulin-Bile Salt Aerosol" Diabetes 32:1040, 1983.			
	EF	Olanoff et al., "Method to Enhance Intranasal Peptide Delivery" American Chemical Society Symposium, Lee & Good, eds., New York, April 13-18, 1986.			
	EG	Pontiroli et al., "Nasal administration of glucagon and human calcitonin to healthy subjects: a comparison of powders..." Eur. J. Clin. Pharmacol. 37:427-430, 1989.			
	EH	SanGiovanni, "Just how practical is aerosolized nasal insulin" Spray Tech. & Marketing 2(1):16-19, 1992.			
	EI	Schipper et al., "Nasal Insulin Delivery with Dimethyl-B-Cyclodextrin as an Absorption Enhancer in Rabbits..." Pharm. Res. 10:682, 1993.			
	EJ	Touitou et al., "Targeted Enteral Delivery of Insulin to Rats" Int. J. Pharm. (AMST) 30:95-100, 1986.			
	EK	Wearley, "Recent Progress in Protein and Peptide Delivery by Noninvasive Routes" Crit. Rev. in Therapeutic Drug Carrier Systems 8(4):331-394, 1991.			
	EL	Wigley et al., "Insulin Across Respiratory Mucosae by Aerosol Delivery" Diabetes 20(8):552, 1971.			
	EM	Yoshida et al., "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form" J. of Pharm. Sciences 68:670, 1979.			
Q.B	EN	Zinman, "The physiologic replacement of insulin" Medical Intelligence: Drug Therapy 321:363, 1989.			
EXAMINER		13awa	DATE CONSIDERED		9/22/98
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					